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(71) Applicant: UROMED CORPORATION [US/US]; 64 A Street, Needham, MA 02194 (US).

(72) Inventors: MAXFIELD-BAHR, Michelle; 1006 Broadway, Somerville, MA 02144 (US). MANZO, Michael, P.; 70 Neptune Street, Beverly, MA 01915 (US). CRUZ, Amos, G.; 25 Vine Street, Franklin, MA 02038 (US). CERIER, Jeffrey, C.; 11 Orchard Street, Franklin, MA 02038 (US). SIMON, John, G.; 150 Appleton Street #1C, Boston, MA 02116 (US).

(74) Agent: LORUSSO, Anthony, M.; Lorusso & Loud, 440 Commercial Street, Boston, MA 02109 (US).

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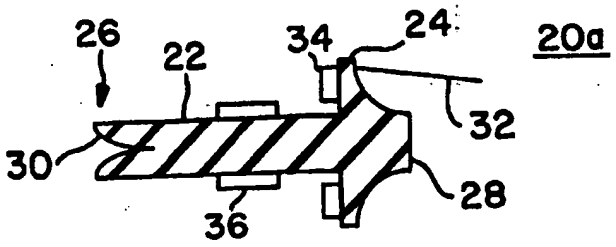
(54) Title: DEVICE AND METHOD TO CONTROL URINARY INCONTINENCE

(57) Abstract

This invention features a urinary occlusion device (20a) having a body member (22) a portion of which is reconfigurable, where the reconfigurable portion (26) improves the sealing and retaining capability of the occlusion device (20a). In one embodiment, the reconfigurable portion (26) furthers engagement between the reconfigurable portion (26) and the urethra and/or bladder neck after insertion. This reconfigurable portion (26) is responsive to the pressure of accumulating urine by expanding outwardly to further engage the urethra and/or bladder neck. In another embodiment, adhesive is applied to the reconfigurable portion (26) and the reconfigurable portion (26) is configured so the adhesive contacts the urethra and/or bladder neck after insertion. In preferred embodiments, the occlusion device further includes a plate (24) member that assists in anchoring the device while preventing migration of the device into the bladder. A therapeutic compound also may be applied to the device. Also featured is a method for controlling urinary incontinence using such a device.



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DEVICE AND METHOD TO CONTROL URINARY INCONTINENCE

This application is a continuation in part of copending applications Serial Number 08/124,267, filed September 20, 1993 now allowed, Serial Number 08/267,487, filed June 29, 1994, and Serial Number 08/478,327, filed June 7, 1995 which is a divisional of Serial Number 07/811,571, filed December 20, 1991 now U.S. Patent No. 5,479,945. The teachings of the foregoing applications are incorporated herein by reference.

DEFINITIONS

The instant invention is most clearly understood with reference to the following definitions:

Surface artifacts shall be understood to mean ribs, grooves and the like which present a broken, roughened or raised surface. This increases the surface area of the occlusion device surfaces available for coaptation with the surrounding tissues. Further, it shall be understood that such surface artifacts may be random, continuous about the circumference, discontinuous about the circumference, uneven or a combination thereof.

Various trademarks appear throughout the specification to describe some of the chemical ingredients or materials of the instant invention. They are identified as follows:

"KRATON G" is a trademark of Shell Oil Company and identifies a styrene-ethylene/butylene styrene block co-polymer blend.

"C-FLEX" is a trademark of Consolidated Polymer Technologies, Inc. and identifies a styrene-ethylene/butylene styrene block co-polymer blend.

"SARLINK" is a trademark of DSM Thermoplastic Elastomers Inc. and identifies a dynamically vulcanized thermoplastic elastomer product.

"SANTOPRENE" is a trademark of Monsanto Company and identifies thermoplastic elastomers and more particularly, styrene block thermoplastic elastomers.

FIELD OF THE INVENTION

This invention relates to urinary occlusion devices and methods for controlling urinary incontinence, and is directed more particularly to a urinary occlusion device and method where the device is inserted into and removed from the urethra by the user.

BACKGROUND OF THE INVENTION

Urinary stress incontinence is the involuntary loss of urine when the pressure within the urethra exceeds the urethral sphincter pressure required for maintaining continence. While the problem of urinary incontinence occurs in men and women, it is an affliction especially common in women of child bearing age and beyond.

There are in existence many methods used to address the problem of incontinence, including surgical corrective techniques (e.g., bladder neck suspension surgery), surgically implanted indwelling devices, physician prescribed and inserted indwelling devices, and external devices. Each method has its drawbacks.

Surgically implanted devices may not be appropriate for patients with mild incontinence, or for those with other medical

conditions that place them at risk for surgery. Additionally, one must consider the cost of surgery. There are also the problems of encrustation, irritation, infection, toxic reactions to materials, and tissue necrosis with surgically implanted devices.

Indwelling devices that are inserted by a physician, without involving surgical implantation, are described in United States Patent Nos. 4,850,963, No. 4,457,299, 4,553,533, 3,797,478, and 3,841,304. These devices are inserted by a physician through the urethral orifice and allow the wearer to void either past or through the device. These devices, because they are indwelling, are often cumbersome to the wearer and may cause some of the numerous complications associated with surgically implanted devices. Additional limitations include problems with component migration into the bladder and problems encountered when the wearer must take cumbersome actions to void or otherwise manipulate the device.

There also are devices that are capable of being inserted by the wearer into the urethra. Such devices are removed for voiding, and then reintroduced into the urethra upon completion of bladder evacuation. Examples of such devices are described by Nielsen, Kurt K. et al., in "The Urethral Plug: A New Treatment Modality for Genuine Urinary Stress Incontinence in Women" J. Urology, vol. 44, p. 1100 (1990) and in United States Patent No. 5,090,424. The device described in the article may be subject to sealing problems. Also, because of the device's configuration and rigidity, there may be problems with comfort and ease of use.

United States Patent No. 5,090,424 discloses a "remove to void" device comprised of a conformable urethral plug. The body of the plug forms a cavity which is in fluid communication with another cavity via a check valve. Fluid may be pumped into the cavity within the urethra to provide a custom fit. This device, like many others relying on liquids or gels for expansion, relies heavily on a fluid-tight valve in order to retain and seal the device in the urethra. Should valve failure occur, evacuation would immediately follow. There is also the chance of fluid leakage into the body of the wearer should rupture of the plug occur.

There is, therefore, still a need for a remove-to-void urinary occlusion device that enhances the ability to retain and seal the device, which is comfortable and easily useable by any individual. In addition, a method is needed for controlling urinary incontinence using such a device.

SUMMARY OF THE INVENTION

It is, therefore, an object of the present invention to improve the retaining and sealing ability of a urinary occlusion device in the urethra and/or bladder neck.

It is another object of the present invention to provide a urinary occlusion device that continuously blocks the flow of urine.

It is a further object of the present invention to provide a urinary occlusion device that improves sealing and anchoring capability in response to increased bladder pressure due to physical body stress, for example, coughing.

It is yet another object of the present invention to provide a urinary occlusion device that is configurable with numerous plate geometries that seal and anchor the device to the tissues surrounding the urinary meatus.

It is yet another object of the present invention to provide a urinary occlusion device that does not require sizing the occlusion device for a given user.

Still another object of the present invention is to provide a urinary occlusion device that can be comfortably and easily inserted into the user's urethra.

Still a further object of the present invention is to provide a method for using a urinary occlusion device to control urinary incontinence.

These and other objects of the invention are carried out by a novel urinary occlusion device including a body member having a reconfigurable portion that is adapted to improve the sealing and retaining capability of the urinary occlusion device. After inserting the occlusion device into the urethra, the reconfigurable portion is configured into an operative condition. In one embodiment, when the reconfigurable portion is in its operative configuration, the engagement between the reconfigurable portion and the surrounding tissues of the urethra and/or bladder neck is enhanced. Moreover, this configuration yields an occlusion device that responds to the pressure of urine accumulating in the urethra, for example, due to an incompetent sphincter.

In another embodiment, the reconfigurable portion includes an adhesive thereon. When the reconfigurable portion is in its operative condition, the adhesive contacts the surrounding tissues of the urethra and/or bladder neck. Sealing and retain-

ing capability of either embodiment may be further enhanced by configuring the body member with surface artifacts, as well as by connecting a plate member with an adhesive thereon, to the body member.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a cross-sectional view of one embodiment of a urinary occlusion device according to the instant invention;

FIG. 1B is a partial breakaway view of the urinary occlusion device of FIG. 1A with the reconfigurable tip expanded;

FIG. 2A is a cross-sectional view of an alternative embodiment of the urinary occlusion device of FIG. 1A;

FIG. 2B is an axonometric view of the urinary occlusion device of FIG. 2A with the reconfigurable tip expanded;

FIG. 2C is a cross-sectional view of a urethra into which is inserted the urinary occlusion device of FIGS. 2A,B;

FIG. 3A is a cross-sectional view of another embodiment of a urinary occlusion device according to the instant invention;

FIG. 3B is a cross-sectional view of a urethra into which is inserted the urinary occlusion device of FIG. 3A;

FIG. 4A is a cross-sectional view of another embodiment of a urinary occlusion device according to the instant invention;

FIG. 4B is a cross-sectional view of an alternative embodiment of the urinary occlusion device of FIG. 4A;

FIG. 4C is a cross-sectional view of an alternative stem for the urinary occlusion device of FIGS. 4A,B;

FIG. 4D is a cross-sectional view of a urethra into which is inserted the urinary occlusion device of FIG. 4A;

FIG. 5A is a cross-sectional view of another embodiment of a urinary occlusion device according to the instant invention;

FIGS. 5B,C are cross-sectional views of a urethra into which are inserted alternative embodiments of the urinary occlusion device of FIG. 5A;

FIGS. 6A-G are views of various plate embodiments for the occlusion devices of the foregoing figures; and

FIG. 7 is a cross-sectional side view of an exemplary urinary occlusion device including a medication dispensing means.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

At the outset, the invention is described in its overall aspects with a more detailed description following. The present invention is a novel urinary occlusion device including a body member having a reconfigurable portion that is adapted to improve the sealing and retaining capability of the device. In one embodiment, the reconfigurable portion, when in its operative configuration, improves or increases the engagement between the reconfigurable portion and the surrounding tissues of the urethra and/or bladder neck. Moreover, this configuration yields an occlusion device that responds to the pressure of urine accumulating in the urethra, for example, due to an incompetent sphincter.

In another embodiment, the reconfigurable portion includes an adhesive thereon. When the reconfigurable portion is in its operative configuration, the adhesive contacts the surrounding tissues of the urethra and/or bladder neck.

The urinary occlusion devices discussed above improve the sealing and retaining capability of the device, while providing an occlusion device which a user can easily and comfortably insert into the urethra. Sealing and retaining capability may be further improved by configuring the body member, including the reconfigurable portion, with surface artifacts. The occlusion devices of the instant invention also may be provided with a means for dispensing therapeutic compounds to the user's urinary tract.

These urinary occlusion devices are advantageous in that the device does not require sizing for a given user; a single sized device may be used for a range of urethral lengths. As such, the tip of a given device may be disposed in the urethra either distal to the sphincter, at the sphincter, or proximal to the sphincter.

The occlusion devices, including any portions thereof, may be formed using a number of manufacturing methods or techniques, such as injection molding, blow molding or extruding. Also, these devices may be made from a number of biocompatible materials, including but not limited to, thermoplastic or thermoset elastomers and similar materials thereto, in particular, KRATON G, C-FLEX, polyurethane, SARLINK, SANTOPRENE, poly-vinyl chloride, silicone, latex or other rubbers.

The configuration (e.g., size and thickness) and the material of the occlusion devices preferably yield devices that are sufficiently flexible as to conform to, and move with, a particular urethra. However, it is within the scope of the instant invention for the occlusion devices to be relatively inflexible.

Referring now to the various figures of the drawing wherein like reference characters refer to like parts, there is shown in FIGS. 1A-B a urinary occlusion device 20a having a body member 22 with a reconfigurable portion 26. Preferably, the body member 22 is solid, however, alternatively it may be hollow. The reconfigurable portion 26 comprises a reconfigurable tip 30 at one end of the body member 22. The reconfigurable tip 30 is constructed from a flexible material that is selectively configurable in either of two configurations. In the first or pre-insertion configuration, the reconfigurable tip 30 of the device 20a is collapsed upon itself (FIG. 1A). Following insertion of the device into the urethra, the reconfigurable tip 30 is configured into a second configuration (FIG. 1B). The reconfigurable tip 30 expands outwardly and contacts the surrounding tissues of the urethra and/or bladder neck.

In the second configuration, as shown in FIG. 1B, the reconfigurable tip 30 forms a cup or truncated cone shape. When so configured, the sides of the reconfigurable tip 30 contact and coapt with the surrounding tissues of the urethra and/or bladder neck. The sides of the reconfigurable tip 30, now in sealing engagement with the surrounding tissues, block the flow of urine.

The sides of the reconfigurable tip 30, in contact with the surrounding tissues, form a chamber 38 whose open end is directed towards the bladder. The flexibility of the tip material allows the walls of the open-ended chamber 38 (i.e., sides of the re-configurable tip 30) to move or expand outwardly to further engage the surrounding tissues of the urethra and/or bladder neck. This motion is responsive to the buildup of

pressure from the urine accumulating in the urethra and is responsive to momentary pressure spikes, such as those caused by coughing, sneezing, laughing or jogging. The enhanced engagement between the reconfigurable tip 30 and the surrounding tissues of the urethra and/or bladder neck furthers the sealing between the urinary occlusion device 20a and the urethra and/or bladder neck. The enhanced engagement also serves to anchor the occlusion device 20a, thereby enabling it to resist expulsion from the urethra, particularly in times of momentary pressure spikes attributable to the physical body stresses described above.

When the bladder pressure returns to its steady or normal state, the pressure of the urine within the open-ended chamber 38 is also reduced. This, in turn, reduces the force being imparted on the surrounding tissues of the urethra and/or bladder neck by the reconfigurable tip 30. Thus, the force that seals and anchors the occlusion device 20a within the urethra corresponds to the pressure of the urine accumulating in the urethra or momentary bladder pressure spikes.

The urinary occlusion device 20a further includes a plate member 24 that is attached to one end of the body member 22. The plate member 24 is a flange type member adapted to anchor the occlusion device 20a at the meatus. To carry out this function of anchoring, the plate member 24 is of a thickness sufficient to withstand bodily compression during wear, preferably on the order of 0.5 millimeter or greater. The plate member 24 prevents the occlusion device 20a from passing through the natural urethral opening ultimately leading into the bladder neck or bladder. The preferred configuration of the plate

member 24 is circular, however, the plate member 24 is configurable with a number of geometries, such as those illustrated in FIGS. 6A-G.

The plate member 24 further includes a layer 34 of adhesive that is applied to at least a portion of the bottom surface of the plate member. The adhesive layer 34 adheres the plate member 24 to the tissues surrounding the urinary meatus after fully inserting the occlusion device 20a into the urethra (i.e., when the plate member 24 abuts the tissues surrounding the urinary meatus). This assures a secure placement of the urinary occlusion device 20a and prevents slippage of the occlusion device from the urethra. When the urinary occlusion device 20a is used by females, the adhesive layer 34 may be applied to the plate member 24 in such a fashion as to anchor and seal it to the tissues surrounding the urinary meatus and/or the interior surfaces of the labia.

Alternatively, or in addition to the plate member adhesive layer 34, at least one adhesive layer 36 is applied to a portion of the body member 22. The illustrated embodiment is only exemplary and a layer of adhesive may be applied to the plate member 24, to the distal, intermediate and/or proximal portion of the body member 22, or any combination thereof. The adhesive layers 34,36 may be continuous, discontinuous, spotty and/or uneven, depending on the degree of adhesion desired. The adhesive layers 34,36 bond with the tissues surrounding the urinary meatus and/or surrounding tissues of the urethra, bladder neck and/or bladder, thereby furthering the conformity of the occlusion device 20a to the surrounding tissues.

The adhesive being applied to the device comprises a hydrogel adhesive. Other suitable adhesives include, but are not limited to, acrylic-based adhesives, synthetic rubber-based adhesives and hydrocolloid adhesives. Alternatively, the adhesive may comprise a combination of adhesives with differing properties, such as those concerning water absorption and initial tackiness. Further, the adhesives may be selected to optimize desired properties, including the efficacy of the desired properties over time. The adhesive also may be selectively applied to the body member 22 and/or plate member 24 to provide a number of areas thereon with different adhesive materials. For example, the layer 34 of adhesive applied to the plate member 24 may be formed from two concentric annular rings of adhesive, each ring including an adhesive having a different property.

The exposed surface of each adhesive layer 34,36 may be covered with a removable protective material, such as a release paper. The removable material is preferably polyester or a coated paper. However, other materials known in the art for removably covering an adhesive are also suitable. The removable material, if any, is removed prior to, during, or after insertion of the urinary occlusion device 20a to expose the tacky surface of the adhesive.

Preferably, the plate member 24 is configured with a handle 28 that extends from the plate member. The handle 28 is integral with the plate member 24. The handle 28 may be configured in any shape and size that allows the user to easily and securely hold the urinary occlusion device 20a and manipulate it to an operable position in the urethra.

Alternatively, if the body member 22 is hollow, the plate member 24 may be configured with a corresponding aperture so the urinary occlusion device can be used with an applicator, such as the applicator 60 in FIG. 3A. The applicator provides a mechanism for the user to manipulate the occlusion device 20a to facilitate placement of the device into an operable position in the urethra. Further, an applicator rod, such as the applicator rod 62 in FIG. 3A, may be used to stiffen the body member 22 to facilitate its insertion into the urethra.

The plate member 24 may be configured with an appendage that extends from the body of the user, after insertion of the urinary occlusion device 20a. The appendage aids in removing the urinary occlusion device when the wearer wishes to void his or her bladder. The appendage may be a ring-like appendage 56, as shown in FIG. 3B, that extends outwardly and across the surface of the plate member 24. Alternatively, the appendage may be a ribbon or string 32 affixed to the plate member 24, as shown in FIG. 1A. Other appendages, such as a tab or extension of the plate member 24, are equally suitable.

Referring now to FIGS. 2A-B, there is shown an alternative and preferred embodiment of a urinary occlusion device 20b. The occlusion device 20b includes an outer member or sheath 40, having a hollow sheath body 42 and a sheath plate member 44. The body member 22 is slidably disposed in the internal passage of the sheath body 42 such that the reconfigurable tip 30 is selectively disposed within the sheath 40 by sliding the body member 22 in the internal passage.

Prior to insertion of the occlusion device 20b into the urethra, a portion of the body member 22 that includes the

reconfigurable tip 30 is disposed in the internal passage of the sheath 40. In this arrangement, the reconfigurable tip 30 is in its collapsed state (FIG. 2A), making insertion of the sheath 40 and the body member 22 enclosed therein, comfortable and easy. The tip 46 of the sheath 40 is preferably rounded to minimize trauma to the surrounding tissues of the urethra and/or bladder neck during insertion of the device.

The sheath 40 and the enclosed body member 22 are inserted into the urethra until the sheath plate member 44 abuts the tissues surrounding the urinary meatus. The user then pushes the handle 28, thereby sliding the body member 22 farther into the sheath 40 until the plate member 24 abuts the surface of the sheath plate member 44. As the body member 22 is slid farther into the sheath 40, the reconfigurable tip 30 passes through the internal passage and out of the aperture 48 in the tip 46. When the reconfigurable tip 30 passes through the aperture 48, the tip 30 automatically and resiliently reconfigures itself into an operative state whereby the sides of the tip 30 contact and coapt with the urethra and/or bladder neck. The reconfiguration of the tip 30 enhances or improves the sealing engagement of the body member 22 with the surrounding tissues and further establishes a configuration responsive to the pressure of urine accumulating in the urethra.

The sheath plate member 44 is adapted to abut the tissues surrounding the urinary meatus as well as to engage the plate member 24. A layer 34,36 of adhesive may be applied either solely to the sheath plate member 44, solely to the sheath body 42, or to both. As with the urinary occlusion device 20a of FIGS. 1A-B, the layers 34,36 of adhesive may be covered with a

removable protective covering. The adhesive on the sheath plate member 44 and/or sheath body 42 seals the urinary occlusion device 20b within the urethra, thereby assuring a secure placement of the occlusion device. Reference should be made to the discussion regarding FIGS. 1A-B for adhesives suitable for use in the invention, as well as the manner in which they are applied to the sheath plate member 44 and/or sheath body 42 (e.g, continuous, discontinuous, etc.).

In addition to the sheath plate member 44 and sheath body 42, the plate member 24 and/or body member 22 may be provided with a layer 34,36 of adhesive, as shown in FIGS. 1A,B. These adhesive layers 34,36 bond the sheath 40 to the plate member 24 and/or body member 22. For example, a layer 34 of adhesive may be applied to the plate member 24 to adhesively secure it to the sheath plate member 44 when the two abut each other. Alternatively, a layer 36 of adhesive may be applied to the body member 22 so as to adhesively secure it within the internal passage of the sheath body 42 after the reconfigurable tip 30 passes through the aperture 48.

The sheath plate member 44 may be provided with an appendage, as described above with reference to FIGS. 1A,B. The appendage extends from the body of the user after insertion of the occlusion device 20b, and aids in removal of the device when the wearer wishes to void his or her bladder. If the sheath 40 is adhesively secured to the body member 22 and/or plate member 24, then the appendage may be secured to the plate member 24.

To remove the urinary occlusion device 20b from the user's body, the handle 28 is manipulated to draw the reconfigurable tip 30 into the sheath 40, thereby returning the tip 30 to its

collapsed state. Thereafter, the user pulls the appendage to break any adhesive seals between the occlusion device 20b and the surrounding tissues of the user. Alternatively, the occlusion device 20b may be removed without drawing the reconfigurable tip 30 into the sheath 40. In this case, the handle 28 and/or appendage of the occlusion device 20b is manipulated to break any adhesive seals. Thereafter, the handle 28 and/or appendage is manipulated to draw the body member 22 from the urethra.

To use the occlusion device 20a,20b, the user removes the device from its packaging (not shown). The user may remove any protective coverings from the adhesive layer 34,36 on the body member 22 and/or plate member 24. As noted above, the protective coverings may be removed during or after insertion of the occlusion device into the urethra. If the occlusion device is configured with, or includes, a treatment layer 250 and/or pellet 252 (FIG. 7), the user also takes those actions required to expose the treatment layer 250/pellet 252 in preparation of inserting the device into the urethra 4.

The body member 22 of the occlusion device 20a,20b is inserted through the natural urethral opening and into the urethra until the plate member 24 securely contacts the tissues surrounding the urinary meatus. In this way, the adhesive layer 34,36 that is applied to the occlusion device contacts the tissues surrounding the urinary meatus and/or surrounding tissues of the urethra and/or bladder neck, thereby securing the device in the user's body.

Following insertion, the reconfigurable tip 30 is configured such that the collapsed tip moves resiliently outwardly to

contact and coapt with the surrounding tissues of the urethra and/or bladder neck. For the urinary occlusion device 20b of FIGS. 2A-C, this is accomplished by the user pushing on the handle 28 such that the collapsed tip passes through the aperture 48 in the sheath 40.

The urinary occlusion device 20a,20b remains within the urethra until the user wishes to void the bladder or unless otherwise directed by a physician. If the plate member 24 is provided with an appendage, the user pulls, twists, or otherwise actuates the appendage 32,56 to break the seals that are anchoring the occlusion device within the urethra. Similarly, if the plate member 24 is configured with a handle 28, the user pulls, pushes or twists the handle to break any seals anchoring the occlusion device within the urethra.

After removing the urinary occlusion device and voiding the bladder, the user prepares and inserts a fresh occlusion device into the urethra. The above described process of preparing, inserting and removing is repeated as needed.

Referring now to FIG. 3A, there is shown another embodiment of a urinary occlusion device 50 having a reconfigurable portion 26 adapted to improve the mechanical retaining and sealing capability of the device 50. As described hereinafter, the reconfigurable portion 26 is invertibly deformed to enhance engagement with the urethra and/or bladder neck after insertion into the urethra. The invertibly deformed reconfigurable portion 26 also is advantageously responsive to the pressure of urine accumulating in the urethra.

The urinary occlusion device 50 includes a hollow body member 22 having a fixed portion 52 and a reconfigurable portion

26. The fixed portion 52 is substantially tubular in shape and is stiffer than the reconfigurable portion 26. The reconfigurable portion 26 includes thin, membrane-like walls having a thickness in the range from about 0.002 to about 0.030 inches. The material comprising the reconfigurable portion 26 and fixed portion 52 is capable of withstanding the stretching of the body member 22, which is preferably done for insertion. At the same time, the material comprising the reconfigurable portion 26 has sufficient flexibility to allow it to be invertibly deformed upon insertion of the device into the urethra.

In an exemplary embodiment, one part of the reconfigurable portion 26 is a hollow conical member and another part of the portion 26 is a hollow cylindrical member, both of which are oriented about a long axis of the occlusion device 50. The outer surface of the hollow cylindrical member may include ribs 55 or other surface artifacts to increase the surface area available for coaptation. The hollow conical member includes a tip 54, preferably rounded, disposed at the vertex of the conical member.

The interior cavity of the tip 54 is designed to engage the end 66 of the applicator rod 62, and to remain engaged as the applicator rod 62 is withdrawn from within the body member 22. In this way, a force is applied to the tip 54 along the long axis of the occlusion device 50 and continues to be applied until the tip cavity and applicator rod end 66 disengage. In one embodiment, disengagement is effected when the tip 54 contacts an inner part of the fixed portion 52, preventing further movement of the tip 54.

The materials of construction, as well as the design of the tip 54, are such that the tip 54 withstands the forces imposed on it as the applicator rod 62 is withdrawn from the body member 22. The materials and design of the tip 54 also enable it to withstand the forces imposed on it by the applicator rod 62 if the body member 22 is stretched for insertion.

Referring to FIG. 3B, when the tip 54 is disengaged from the rod end 66, the hollow conical portion is inverted and disposed within the hollow cylindrical member of the reconfigurable portion 26. When the reconfigurable portion 26 is so inverted, it loses its relaxed shape or configuration. For example, the reconfigurable portion 26 is transposed from its conical configuration, as illustrated in FIG. 3A, to form a cup-like or an open-ended chamber configuration, as illustrated in FIG. 3B. The reconfigurable portion 26 is now invertibly deformed.

When invertibly deformed, the outside surfaces of the reconfigurable portion 26 move radially outwardly to engage the urethra and/or bladder neck. This radial motion increases the engagement between the reconfigurable portion 26 and the surrounding tissues of the urethra and/or bladder neck. This further seals the occlusion device 50 within the urethra and blocks the flow of urine therefrom. The enhanced engagement also serves to anchor the urinary occlusion device 50 within the urethra.

As indicated above, when the reconfigurable portion 26 is invertibly deformed, it forms an open-ended chamber 58, which faces the bladder 2. Similar to the urinary occlusion devices 20a,b of FIGS. 1-2, this open-ended chamber 58 is responsive to the buildup of pressure from urine accumulating in the urethra.

It is also responsive to momentary bladder pressure spikes attributable to physical body stresses, such as those caused by coughing, sneezing, laughing or jogging.

The urinary occlusion device 50 also includes a flange type plate member 24, which prevents migration of the occlusion device into the bladder. The plate member 24 preferably includes a circular configuration, but may be of any geometry, including those described below in connection with FIGS. 6A-G. In addition, the plate member 24 includes an appendage, such as a ring or string, that extends from the body of the user after insertion of the urinary occlusion device 50. The appendage also aids in removal of the urinary occlusion device when the wearer wishes to void his or her bladder. Reference should be made to the foregoing discussion regarding FIGS. 1A-B for further teachings concerning the plate member, which are equally applicable to the occlusion device 50.

As with the occlusion device 20a,b (FIGS. 1A,2A), a layer 34,36 of adhesive may be applied to either the plate member 24 alone, to the body member 22 alone, or to both the plate member 24 and body member 22. These layers 34,36 of adhesive may be covered with a removable protective covering. The adhesive seals the occlusion device 50 within the urethra, thereby assuring a secure placement of the device. Reference should be made to the discussion regarding FIGS. 1A-B for adhesives suitable for use in the invention, as well as the manner in which they are applied to the plate member 24 and/or body member 22 (e.g, continuous, discontinuous, etc.).

The method of using the occlusion device 50 is substantially

similar to the method of using the occlusion device 20a,b, except as provided below.

Prior to insertion, the occlusion device 50 is mounted upon the applicator 60. Preferably, this is done prior to shipment to ease and simplify use of the urinary occlusion device. However, if not so mounted, the user mounts the occlusion device 50 onto the applicator 60. This involves inserting the applicator rod 62 into the plate member opening and internal passage of the body member 22 until the rod 62 reaches and engages the cavity in the tip 54.

It may be desirable to stretch the body member 22 longitudinally prior to insertion to reduce the cross section of the body member. Thus, the user actuates the applicator 60 (e.g., depresses a plunger) to stretch the body member 22, in particular the reconfigurable portion 26. Reducing the cross section eases insertion of the body member 22 into the urethra 4 while minimizing the risk of trauma to the urethral walls and associated tissues.

Following insertion of the occlusion device 50, the user withdraws the applicator rod 62 from the internal passage of the body member 22. Withdrawing the applicator rod 62 causes the re-configurable portion 26 to be invertibly deformed, as hereinabove described.

Referring to FIGS. 4A,4D, there is shown a urinary occlusion device 100 having a body member 22 with a reconfigurable portion 26 onto which is applied an adhesive. In particular, the occlusion device 100 includes a hollow body member 22 having a tip 102 that is reconfigurable, and a stem 112 that is slidably disposed in an interior passage 118 of the body member

22. The tip 102 is selectively reconfigurable between a first and a second configuration. In the first configuration, the tip 102 is inverted, as shown in FIG. 4A. The tip 102 generally presents an atraumatic shape to make insertion of the body member 22 into the urethra comfortable, as well as to minimize the risk of damage to the surrounding tissues. When configured in its second configuration, as illustrated by the dotted lines in FIG. 4A, the tip 102 presents a rounded shape that is exposed to the surrounding tissues of the urethra and/or bladder neck.

The tip 102 is moved selectively between the first and second configurations by means of the stem 112, one end 114 of which contacts the inside surface of the tip 102. The occlusion device 100 is preferably supplied to the user with the tip 102 in its first configuration. In this configuration, the stem 112 extends from the opening 110 in the plate member 24.

To place the tip 102 into its second configuration, the user pushes the stem 112 to advance it into the body member 22. This movement of the stem 112 causes the tip 102 to unfold or roll out, thereby placing the tip 102 into its second configuration. Preferably, the stem 112 is now removed from the occlusion device 100. Alternatively, the stem 112 may remain disposed within the body member 22 and flush with the surface of the plate member 24.

An adhesive layer 106 is applied to the reconfigurable tip 102 such that the adhesive layer is disposed in the depressed region 104 when the tip 102 is in its first configuration. This effectively shields the adhesive layer 106 from contact with the surrounding tissues of the urethra and/or bladder neck as the body member 22 is being inserted into the urethra.

When the tip 102 is in its second configuration, the adhesive layer 106 is exposed within the urethra and/or bladder neck and contacts the surrounding tissues. The adhesive layer 106 seals the urinary occlusion device 100 within the urethra, thereby assuring a secure placement of the occlusion device. The adhesive layer 106 also bonds with the surrounding tissues of the urethra and/or bladder neck, thereby enhancing the conformity of the occlusion device 100 with the urethra and/or bladder neck.

To aid in the removal of the urinary occlusion device 100 from the urethra, an appendage 108 is secured to the inside surface of the tip 102. The appendage 108 may be a string, ribbon or any other shape or configuration that meets the intended use. The appendage 108 extends exterior to the urinary meatus when the occlusion device is positioned in the urethra.

When the user pulls the appendage 108, the tip 102 is returned to its first, inverted configuration. The re-inversion of the tip 102 causes the seal between the adhesive layer 106 and the surrounding tissues to be broken. Since the adhesive layer 106 is no longer exposed, it should not contact and adhere to the surrounding tissues during removal of the occlusion device 100.

The occlusion device 100 includes a flange type plate member 24 that prevents migration of the occlusion device 100 into the bladder. The plate member 24 preferably includes a circular configuration but may be of any geometry, including those described below in connection with FIGS. 6A-G. The plate member 24 may be configured with an appendage to aid in the removal of the occlusion device 100.

In addition, the plate member 24 may include a layer 34 of adhesive. This adhesive layer 34 is capable of bonding with the meatal tissues to enhance the sealing and anchoring of the urinary occlusion device 100. Reference should be made to the discussion regarding FIGS. 1A-B for adhesives suitable for use in the invention, as well as the manner in which they are applied to the reconfigurable tip 102 and/or the plate member 24.

Referring to FIG. 4B, in another embodiment of the occlusion device 100, the stem 112 is secured to the inside surface of the tip 102. The stem 112 remains disposed within the body member 22 after the tip is in its second configuration. For this embodiment, the appendage 108 is affixed to the stem to aid in removal of the occlusion device 100 from the urethra. Thus, when the user pulls the appendage 108, the stem is withdrawn from the body member 22, thereby causing the tip 102 to return to its first configuration.

Referring to FIG. 4C, there is shown an alternative embodiment of a stem 112a in which the end 114 includes an elastomer body 116 that resiliently expands outwardly. Thus, when the stem 112a is inserted into the body member 22 and the tip 102 placed in its second configuration, the elastomer body 116 urges the tip 102 outwardly to maintain contact between the adhesive layer 106 and the surrounding tissues. The elastomer body 116 thus enhances the sealing and anchoring capability between the adhesive layer 106 and the surrounding tissues. It is also within the scope of the instant invention for the elastomer body 116 to cause the tip 102 to expand radially outwardly to enhance the engagement between the body member 22 and the urethra and/or

bladder neck, thereby further occluding the urethra. In a further embodiment, the elastomer body 116 is separable from the stem 112a, so the elastomer body remains disposed within the tip 102 after removing the stem 112a from the urinary occlusion device 100.

Referring next to FIG. 5A, there is shown a cross-sectional view of another embodiment of the invention. The urinary occlusion device 120 includes a body member 22, a portion 26 of which is reconfigurable and onto which is applied a layer 124 of adhesive. This urinary occlusion device 120 includes a plate member 24 and a stem 112 that is slidably disposed in the interior passage 118 of the hollow body member 22. The body member 22 also includes a tip 128. The body is oriented to be generally symmetrical about a long axis of the occlusion device 120.

The reconfigurable portion 26 includes at least one groove, indentation or depressed region 122 in which a layer 124 of adhesive is disposed. The adhesive layer 124 and its corresponding depressed region 122 are arranged such that the adhesive layer lies below the outside surface of the body member 22. This effectively shields the adhesive layer 124 from contact with the urethra and/or bladder neck as the body member 22 is inserted into the urethra. As illustrated in FIG. 5C, the reconfigurable portion 26 may include a plurality of depressed regions 122, each region having a layer 124 of adhesive disposed therein.

Each depressed region 122 is forced outwardly by the stem 112 as it slides in the interior passage of the body member 22. The diameter of the stem 112 is sized so that as the stem 112

slides, its outside surface acts on the inside surface of each depressed region 122, thereby forcing each depressed region outwardly. Since the stem 112 projects exteriorly from the plate member 24, it can be used as a handle to insert the occlusion device 120 into the urethra.

Forcing each depressed region 122 outwardly causes the adhesive layer 124 in each region to contact the surrounding tissues of the urethra and/or bladder neck. When the adhesive layer 124 contacts the surrounding tissues, the adhesive layer 124 seals the urinary occlusion device 120 within the urethra and/or bladder neck. This assures a secure placement of the occlusion device 120. The bonding of the adhesive layer(s) 124 with the surrounding tissues enhances the conformity of the occlusion device 120 with the urethra and/or bladder neck.

The stem 112 preferably is removed from the body member 22 after the depressed region 122 has been forced outwardly and the adhesive layer 124 placed in contact with the surrounding tissues. It is within the scope of the present invention, however, for the stem 112 to remain disposed within the body member 22 to maintain the outward displacement of the depressed region 122.

To assure maintenance of the outward displacement of the depressed region 122, one end of the stem 112 may include an elastomer body that resiliently expands outwardly. Thus, when the stem 112 is fully inserted within the body member 22, the elastomer body urges each depressed region 122 outwardly to maintain and enhance the contact of each adhesive layer 124 with the surrounding tissues. It is also within the scope of the instant invention for the elastomer body to cause the tip 128 to expand radially outwardly and engage the urethra and/or bladder

neck. In a further embodiment, the elastomer body may be separable from the stem 112, thus remaining within the body member 22 after the stem 112 is withdrawn.

To aid in the removal of the occlusion device 120, an appendage 126 is secured to the inside surface of the tip 128. The appendage 126 may be a string, ribbon or any other shape or configuration that meets the intended use. The length of the appendage 126 is such that the appendage extends exterior to the urinary meatus when the occlusion device is inserted into the urethra. When the user pulls the appendage 126, the body member tip 128 and the reconfigurable portion 26 are inverted and drawn within the body member 22. Inversion of the reconfigurable portion 26 causes each adhesive layer 124 to break contact with the surrounding tissues. Thus, the occlusion device 120 is easily removed from the urethra.

In an alternative embodiment, the appendage 126 passes through a passage 130 (see dashed lines of FIG. 5A) in the stem 112. Thus, when the user pulls on the appendage 126, the inversion of the tip 128 and reconfigurable portion 26 pushes the stem 112 from the body member 22. Similarly, in the embodiment in which the elastomer body is separable from the stem, the elastomer body is pushed from the body member 22 when the user pulls on the appendage 126.

The plate member 24 is a flange type member which prevents migration of the occlusion device 120 into the bladder. Reference should be made to the discussion concerning FIGS. 1A-B for further teachings concerning the plate member, which are equally applicable to the occlusion device 120. Reference also should be made to the discussion regarding FIGS. 1A-B for adhesives

suitable for use in the invention, as well as the manner in which they are applied to each depressed region 122 and/or the plate member 24.

The method of using the respective occlusion devices 100,120 described in FIGS. 4-5 is substantially similar except with regard to the method for their removal, which will be addressed below. The urinary occlusion device 100,120 is removed from its packaging (not shown) by the user and is prepared for insertion in the manner described for the occlusion devices of FIGS. 1-2. If the stem 112,112a is not already disposed within the body member, preparation also includes mounting the body member upon the stem.

The user inserts the body member 22 through the natural urethral opening into the urethra 4, using the stem 112,112a as a handle. The user advances the body member 22 into the urethra 4 until the bottom surface of the plate member 24 securely contacts the tissues surrounding the urinary meatus.

After fully inserting the body member 22 into the urethra 4, the user pushes the stem 112,112a farther into the interior passage of the body member 22. As described in the foregoing, the reconfigurable portion 26 is configured in its second configuration whereupon the adhesive on the portion 26 contacts the surrounding tissues of the urethra and/or bladder neck. The user preferably now removes the stem 112,112a from the body member 22.

The urinary occlusion device remains within the urethra 4 until the user wishes to void the bladder or unless otherwise directed by a physician. As illustrated in FIG. 4D, to remove the urinary occlusion device 100 having a reconfigurable tip

102, the user pulls the appendage 108, thereby causing the tip 102 to return to its inverted first configuration. As illustrated in FIG. 5C, to remove the urinary occlusion device 120 having at least one depressed region 122, the user pulls the appendage 126 causing the tip 128 and the reconfigurable body portion 26 to be drawn into the body member 22. In both embodiments, such pulling breaks the seal between the adhesive layer 106,124 and the surrounding tissues. The adhesive layer 106,124 is essentially shielded from contact with the urethra and/or bladder neck as the occlusion device is removed.

The user continues to pull the appendage 108,126 to remove the occlusion device from the urethra. Alternatively, the user may pull, twist, or otherwise actuate the plate member appendage to remove the device after the reconfigurable portion 26 is reconfigured for removal. It is within the scope of the instant invention, however, for a user to remove the occlusion device from the urethra without reconfiguring the reconfigurable portion 26. The user would break the seals that are anchoring the occlusion device within the urethra and remove the device by simply actuating the plate member appendage.

After removing the urinary occlusion device 100,120 and voiding the bladder, the user prepares and inserts a fresh occlusion device into the urethra. The above described process of preparing, inserting and removing is repeated as needed.

Referring to FIGS. 6A-G, any of the above described occlusion devices are configurable with the plate member geometries illustrated in FIGS. 6A-G. The illustrated plate members are suitable to anchor the described occlusion devices to the tissues surrounding the urinary meatus. The geometry of the

plate members 200a-g are exemplary and are not intended to include every possible plate geometry. The geometry of a plate member is dependent upon various factors such as the user's comfort, the ability of the design to be anchored and sealed, gender, ease of insertion, and the method for removing the occlusion device from the urethra.

FIGS. 6A-C show the preferred circular plate members 200a-c. In the pre-insertion state, the circular plate member is either flat (FIG. 6A) or provided with a three dimensional contour (FIGS. 6B,C). Because of anatomical differences, the convex circular plate member 200b is primarily for use by females and the concave plate member 200c is primarily for use by males. Other plate member geometries include a dumbbell-shaped plate member 200d (FIG. 6D); an ovoid-shaped plate member 200e (FIG. 6E); a star-shaped plate member 200f (FIG. 6F); and a bow tie-shaped plate member 200g (FIG. 6G).

The plate geometries may comprise a three dimensional contour or may include fold lines to improve the conformability of the plate member to the tissues surrounding the urinary meatus and/or the labia. For example, a flat circular plate member 200a may be configured with two essentially parallel foldlines so the portions outboard of each foldline are rotatable to form downwardly extending sides.

Referring to FIG. 7, there is shown a urinary occlusion device that is capable of delivering therapeutic compounds to the urinary tract and/or bladder. The lower urinary tract, as well as the urethra and bladder, are subject to a variety of disorders and/or bacterial infections. The urinary occlusion device may deliver therapeutic compounds to those suffering from

existing disorders and/or infections, as well as to those in need of prophylaxis to minimize the risk of developing such disorders. While the delivery system is described in connection with one particular occlusion device of the invention, any of the occlusion devices illustrated in FIGS. 1-5, and described above, are suitable for use as a vehicle to deliver therapeutic compounds.

Bacterial infections and other disorders in the urine and/or superficial regions of the urethral and bladder tissues are, in most situations, highly amenable to treatment by the direct release of antibiotics or other therapeutic compounds into the urine or urethral walls. Effective therapeutic compounds include, but are not limited to, sulfonamides, tetracycline, ampicillin, amoxicillin, trimethoprim, trimethoprim/sulfamethoxazole, and ciprofloxacin hydrochloride. These compounds may be dispersed in a soluble solution as is known in the art (see also copending application Serial No. 08/478,327).

The urinary occlusion device 50a is provided with a treatment layer 250 of antibiotics or other therapeutic compounds that are dispersed in a solution with a binder. The treatment layer 250 is applied to the urinary occlusion device 50a to coat one or more portions of the outer surface of the body member 22. For example, the treatment layer 250 may be applied to that part of the reconfigurable portion 26 intended to contact the surrounding tissues of the urethra. Further, each treatment layer 250 that is applied can include different therapeutic compounds, and the layers can be applied to different portions of the body member 22. To control the release or dissolution of the therapeutic compounds, a permeable membrane or heat-shrink-

able silicone membrane, may be applied over the treatment layer 250.

Alternatively, or in combination with the above described treatment layer 250, a pellet 252 containing the therapeutic compounds is attached to the body member 22. In the illustrated embodiment, the pellet 252 is attached or bonded to the tip 54 using, for example, cyanoacrylate glue. Thus, when the reconfigurable portion 26 is invertibly deformed, the pellet 252 is within the chamber 58 and in fluid communication with urine accumulating in the urethra and/or bladder. The medication is thus dispersed into the urine.

The treatment layer 250 or pellet 252 may include a pain medicament, such as benzocaine and lidocaine. The pain medicament is provided in the treatment layer 250 and/or pellet 252. It may be provided in combination with other pain medicaments, or in combination with the therapeutic compounds hereinabove described. Such pain medication is used primarily to numb the tissues within the urethra and/or bladder neck during and following insertion of the occlusion device of the invention.

While preferred embodiments of the invention have been described using specific terms, such descriptions are for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims, giving due regard for those changes that are obvious to those skilled in the art, including other techniques for delivering the therapeutic compounds using the urinary occlusion device of the instant invention.

What is claimed is:

1. A urinary occlusion device comprising:

a body member, a portion of said body member being reconfigurable; and

wherein said reconfigurable portion is configured to enhance engagement between said reconfigurable portion and the surrounding tissues of at least one of the urethra and bladder neck.

2. The urinary occlusion device of claim 1, wherein said reconfigurable portion when so configured is responsive to pressure of urine accumulating in the urethra and wherein said reconfigurable portion is adapted to expand outwardly in response to increases in urine pressure.

3. The urinary occlusion device of claim 1, further comprising an adhesive applied to at least a portion of said urinary occlusion device to retain said body member in the urethra.

4. The urinary occlusion device of claim 1, further comprising a plate member, wherein said body member is connected to said plate member and extends therefrom.

5. The urinary occlusion device of claim 4, further comprising an adhesive applied to at least a portion of said plate member to secure said plate member to tissues surrounding the urinary meatus.

6. The urinary occlusion device of claim 4, wherein said plate member has a configuration selected from the group consisting of a circular plate member, a dumbbell-shaped plate member, an ovoid-shaped plate member, a star-shaped member and a bow tie-shaped member.

7. The urinary occlusion device of claim 1, further comprising an appendage attached to a portion of said urinary occlusion device and being used to remove said body member from the urethra.

8. The urinary occlusion device of claim 1, wherein said body member includes an outer surface and wherein at least a portion of said outer surface includes surface artifacts that improve sealing between said body member and the surrounding tissues.

9. The urinary occlusion device of claim 1, further comprising a therapeutic compound on at least a portion of said body member.

10. The urinary occlusion device of claim 3, wherein said adhesive comprises a plurality of adhesive materials, each adhesive material having differing properties.

11. The urinary occlusion device of claim 10, wherein said plurality of adhesive materials is selected to optimize adhesion over time.

12. The urinary occlusion device of claim 1, further comprising an applicator being coupled to said body member so said body member is insertible into the urethra by a user.

13. The urinary occlusion device of claim 12, wherein said applicator is manipulated by the user so as to place the urinary occlusion device into an operative position.

14. The urinary occlusion device of claim 1, wherein said reconfigurable portion of said body member comprises:

a reconfigurable tip at one end of said body member; and

wherein said reconfigurable tip is configured to form an open-ended chamber after said body member is inserted into the urethra, said open-ended chamber having sides that further engagement and coaptation between said reconfigurable tip and the surrounding tissues.

15. The urinary occlusion device of claim 14, wherein said open-ended chamber is adapted to expand outwardly in response to increases in urine pressure to further engage the surrounding tissues.

16. The urinary occlusion device of claim 1, wherein said body member comprises:

an outer member having an internal passage therethrough;

an inner member slidably received in said internal passage;

wherein said reconfigurable portion comprises a reconfigurable tip of said inner member; and

wherein in one configuration of said body member, said reconfigurable tip extends outwardly from an aperture in one end of said outer member and is configured to engage and coapt with the surrounding tissues.

17. The urinary occlusion device of claim 16, wherein said reconfigurable tip is adapted to expand outwardly in response to increases in bladder pressure to further engage the surrounding tissues.

18. The urinary occlusion device of claim 16, wherein said reconfigurable tip is disposed within said internal passage while said body member is being inserted into the urethra, whereupon said insertion, said inner member is slid in said internal passage to cause said reconfigurable tip to pass out through said outer member aperture.

19. The urinary occlusion device of claim 1, wherein said reconfigurable portion of said body member is adapted to be invertibly deformed when a force is applied to said reconfigurable portion along a long axis of said body member.

20. The urinary occlusion device of claim 19, wherein the invertibly deformed configuration causes a part of said reconfigurable portion to move outwardly to further engage the surrounding tissues.

21. The urinary occlusion device of claim 20, wherein the invertibly deformed configuration expands outwardly in response to increases in bladder pressure to further engage the surrounding tissues.

22. The urinary occlusion device of claim 19, wherein said reconfigurable portion is invertibly deformed after said body member is inserted into the urethra.

23. A urinary occlusion device comprising:

a body member; and

an adhesive applied to at least a portion of said body member to secure said body member to surrounding tissues of at least one of the urethra and bladder neck.

24. The urinary occlusion device of claim 23,

wherein a portion of said body member is reconfigurable;

wherein said adhesive is applied to at least a part of said reconfigurable portion; and

wherein said reconfigurable portion is configured so said adhesive contacts the surrounding tissues after said body member is inserted into the urethra.

25. The urinary occlusion device of claim 24, further comprising a plate member, wherein said body member is connected to said plate member and extends therefrom.

26. The urinary occlusion device of claim 25, further comprising an adhesive applied to at least a portion of said plate member to secure said plate member to tissues surrounding the urinary meatus.

27. The urinary occlusion device of claim 25, wherein said plate member has a configuration selected from the group consisting of a circular plate member, a dumbbell-shaped plate member, an ovoid-shaped plate member, a star-shaped member and a bow tie-shaped member.

28. The urinary occlusion device of claim 24, further comprising an appendage attached to a portion of said urinary occlusion device and being used to remove said body member from the urethra.

29. The urinary occlusion device of claim 24, wherein said body member includes an outer surface and wherein at least a portion of said outer surface includes surface artifacts that improve sealing between said body member and the surrounding tissues.

30. The urinary occlusion device of claim 24, further comprising a therapeutic compound on at least a portion of said body member.

31. The urinary occlusion device of claim 24, wherein said adhesive comprises a plurality of adhesive materials, each adhesive material having differing properties.

32. The urinary occlusion device of claim 31, wherein said plurality of adhesive materials is selected to optimize adhesion of said reconfigurable body portion to the surrounding tissues over time.

33. The urinary occlusion device of claim 26, wherein said adhesive applied to said plate member comprises a plurality of adhesive materials, each adhesive material having differing properties.

34. The urinary occlusion device of claim 33, wherein said plurality of adhesive materials is selected to optimize adhesion of said plate member to the tissues surrounding the urinary meatus over time.

35. The urinary occlusion device of claim 24, further comprising an applicator being coupled to said body member so said body member is insertible into the urethra by a user.

36. The urinary occlusion device of claim 35, wherein said applicator is manipulated by the user so as to place the urinary occlusion device into an operative position.

37. The urinary occlusion device of claim 24, further comprising a mechanism to configure said reconfigurable portion so said adhesive applied to said reconfigurable portion contacts the surrounding tissues.

38. The urinary occlusion device of claim 24, further comprising a removal mechanism actuated by a user to remove said body member from the urethra.

39. The urinary occlusion device of claim 38, wherein said removal mechanism re-configures said reconfigurable portion so said adhesive applied to said reconfigurable portion does not contact the surrounding tissues as said body member is being withdrawn from the urethra.

40. The urinary occlusion device of claim 38, wherein said removal mechanism includes a string affixed to said body member and extending externally from the urinary meatus of the user.

41. The urinary occlusion device of claim 24,

wherein said body member includes a plurality of reconfigurable portions;

wherein said adhesive is applied to at least a part of each reconfigurable portion; and

wherein said plurality of reconfigurable portions are configured so said adhesive contacts the surrounding tissues after said body member is inserted into the urethra.

42. The urinary occlusion device of claim 24, wherein said reconfigurable portion comprises:

a reconfigurable tip at one end of said body member;

wherein said adhesive is applied to at least a portion of said reconfigurable tip; and

wherein said reconfigurable tip is configured so said adhesive contacts the surrounding tissues after said body member is inserted into the urethra.

43. The urinary occlusion device of claim 42, wherein said reconfigurable tip is configured with an inverted shape for insertion of said body member into the urethra, and wherein said adhesive is applied to said reconfigurable tip so said adhesive is essentially shielded while said body member is being inserted into the urethra.

44. The urinary occlusion device of claim 42, further including a mechanism that acts on said reconfigurable tip to configure said reconfigurable tip so said adhesive contacts the surrounding tissues.

45. The urinary occlusion device of claim 44, wherein said reconfiguring mechanism is a stem slidably disposed in a passage in said body member.

46. The urinary occlusion device of claim 42, further comprising a removal mechanism actuated by a user to remove said body member from the urethra, wherein said removal mechanism reconfigures said reconfigurable tip so said adhesive does not contact the surrounding tissues as said body member is being withdrawn from the urethra.

47. The urinary occlusion device of claim 24, wherein said body member includes an outer surface and wherein said reconfigurable portion comprises:

at least one reconfigurable depression in the outer surface;

wherein said adhesive is applied to form an adhesive layer over at least a portion of said at least one reconfigurable depression; and

wherein each of said at least one reconfigurable depression is configured so said adhesive layer contacts the surrounding tissues after said body member is inserted into the urethra.

48. The urinary occlusion device of claim 47, further including a mechanism that acts on said at least one reconfigurable depression so said adhesive layer contacts the surrounding tissues.

49. The urinary occlusion device of claim 48, wherein said mechanism is a stem slidably disposed in an internal passage in said body member;

wherein a portion of said at least one reconfigurable depression extends into the internal body passage; and

wherein said at least one reconfigurable depression is configured so said adhesive layer contacts the surrounding tissues by the engagement of said stem with the portion of each reconfigurable depression in the internal body passage as said stem slides in the internal body passage.

50. The urinary occlusion device of claim 47, wherein said adhesive layer and said at least one reconfigurable depression are arranged so said adhesive layer is essentially shielded from contact with the surrounding tissues as said body member is being inserted into the urethra.

51. A method for controlling urinary incontinence, said method comprising the steps of:

providing a urinary occlusion device including a body member, a portion of which is reconfigurable;

inserting the occlusion device into the urethra of a wearer, in a position such that it blocks the flow of urine; and

configuring the reconfigurable portion so at least a part of the reconfigurable portion engages surrounding tissues of at least one of the urethra and bladder neck.

52. The method for controlling urinary incontinence of claim 51 wherein the occlusion device further includes an adhesive applied to at least a portion of the occlusion device; and

in which said method further comprises the step of adhesively securing a portion of the occlusion device to a user's body to retain the urinary occlusion device in place.

53. The method for controlling urinary incontinence of claim 51 wherein the occlusion device further includes:

a plate member connected to the body member, and

an adhesive applied to at least a portion of the plate member; and

in which said method further comprises the step of adhesively securing the plate member to tissues surrounding the urinary meatus to retain the urinary occlusion device in place.

54. The method for controlling urinary incontinence of claim 51 wherein said step of configuring includes configuring the reconfigurable portion so it is adapted to expand outwardly in response to pressure of urine accumulating in the urethra.

55. The method for controlling urinary incontinence of claim 51, wherein the occlusion device further includes a therapeutic compound and in which said method further comprises the step of dispensing the therapeutic compound to a user's body.

56. The method for controlling urinary incontinence of claim 51 further comprising the step of removing the occlusion device from the urethra to void.

57. The method for controlling urinary incontinence of claim 51 wherein the reconfigurable portion comprises a reconfigurable tip at one end of the body member, and wherein said step of configuring includes configuring the reconfigurable tip to form an open-ended chamber having sides that engage the surrounding tissues.

58. The method for controlling urinary incontinence of claim 57 wherein the open-ended chamber is adapted to expand outwardly in response to pressure of urine accumulating in the urethra, thereby furthering engagement with the surrounding tissues.

59. The method for controlling urinary incontinence of claim 57 further comprising the step of removing the occlusion device from the urethra to void.

60. The method for controlling urinary incontinence of claim 51 wherein the body member includes an inner and outer member; wherein the reconfigurable portion comprises a reconfigurable tip at one end of the inner member; and wherein said step of configuring includes arranging the inner and outer members so the reconfigurable tip forms an open-ended chamber having sides that engage the surrounding tissues.

61. The method for controlling urinary incontinence of claim 60 wherein the open-ended chamber formed is adapted to expand outwardly in response to pressure of urine accumulating in the urethra, thereby furthering engagement with the surrounding tissues.

62. The method for controlling urinary incontinence of claim 60 wherein the inner member is slidably disposed in the outer member having an aperture in one end thereof; and wherein said step of arranging includes sliding the inner member with respect to the outer member so the reconfigurable tip passes through the outer member aperture, whereupon the reconfigurable tip forms the open-ended chamber.

63. The method for controlling urinary incontinence of claim 60 further comprising the step of removing the occlusion device from the urethra to void.

64. The method for controlling urinary incontinence of claim 62 further comprising the steps of:

drawing the reconfigurable tip into the outer member; and

removing the reconfigured device from the urethra to void.

65. The method for controlling urinary incontinence of claim 51 wherein the reconfigurable portion is adapted to be invertibly deformed and wherein said step of configuring includes invertibly deforming the reconfigurable portion, whereupon part of the invertibly deformed reconfigurable portion moves outwardly to engage the surrounding tissues.

66. The method for controlling urinary incontinence of claim 65 wherein the invertibly deformed reconfigurable portion is adapted to expand outwardly in response to pressure of urine accumulating in the urethra to further engage the surrounding tissues.

67. The method for controlling urinary incontinence of claim 65 further comprising the step of removing the occlusion device from the urethra to void.

68. A method for controlling urinary incontinence, said method comprising the steps of:

providing a urinary occlusion device including a body member and an adhesive applied to at least a portion of the body member;

inserting the occlusion device into the urethra of a wearer, in a position such that it blocks the flow of urine; and

adhesively securing said body member to surrounding tissues of at least one of the urethra and bladder neck to retain the occlusion device in place without the movement or slippage thereof from the inserted position.

69. The method for controlling urinary incontinence of claim 68 wherein a portion of the body member is reconfigurable; wherein the adhesive is applied to at least a part of the reconfigurable portion; and wherein said step of adhesively securing includes configuring the reconfigurable portion so the adhesive contacts the surrounding tissues.

70. The method for controlling urinary incontinence of claim 68 wherein the body member being provided includes a plurality of reconfigurable portions; wherein the adhesive is applied to at least a part of each reconfigurable portion; and wherein said step of adhesively securing includes configuring each reconfigurable portion so the adhesive applied thereto contacts the surrounding tissues.

71. The method for controlling urinary incontinence of claim 69 further comprising the steps of:

re-configuring the reconfigurable portion for removal; and

removing the reconfigured device from the urethra to void.

72. The method for controlling urinary incontinence of claim 71 wherein said step of reconfiguring includes reconfiguring the reconfigurable portion so the adhesive applied thereto does not contact the surrounding tissues as the body member is being withdrawn from the urethra.

73. The method for controlling urinary incontinence of claim 69 wherein the reconfigurable portion of the occlusion device is initially configured so the adhesive applied does not contact the surrounding tissues during said step of insertion.

74. The method for controlling urinary incontinence of claim 69, wherein the occlusion device further includes a therapeutic compound and in which said method further comprises the step of dispensing the therapeutic compound to a user's body.

75. The method for controlling urinary incontinence of claim 69 wherein the reconfigurable portion comprises a reconfigurable tip at one end of the body member; wherein the adhesive is applied to at least a part of the reconfigurable tip; and wherein said step of configuring includes configuring the reconfigurable tip so the adhesive applied thereto contacts the surrounding tissues.

76. The method for controlling urinary incontinence of claim 75 further comprising the steps of:

re-configuring the reconfigurable tip for removal; and

removing the reconfigured device from the urethra to void.

77. The method for controlling urinary incontinence of claim 76 wherein said step of re-configuring includes re-configuring the reconfigurable tip so the adhesive applied thereto does not contact the surrounding tissues as the body member is withdrawn from the urethra.

78. The method for controlling urinary incontinence of claim 69 wherein the reconfigurable portion comprises at least one reconfigurable depression in an outer surface of the body member; wherein the adhesive is applied to at least a part of each of the at least one reconfigurable depression; and wherein said step of configuring includes configuring each of the at least one reconfigurable depression so the adhesive applied thereto contacts the surrounding tissues.

79. The method for controlling urinary incontinence of claim 78 further comprising the steps of:

re-configuring the body member for removal; and

removing the reconfigured device from the urethra to void.

80. The method for controlling urinary incontinence of claim 79 wherein said step of re-configuring includes reconfiguring the at least one reconfigurable depression so the adhesive applied thereto does not contact the surrounding tissues as the body member is withdrawn from the urethra.

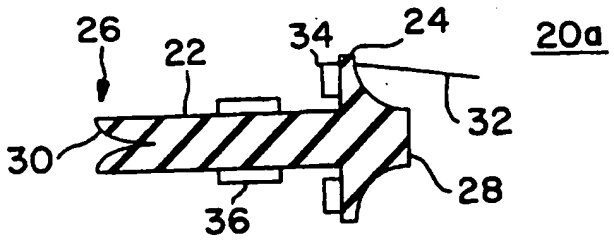

FIG. 1A

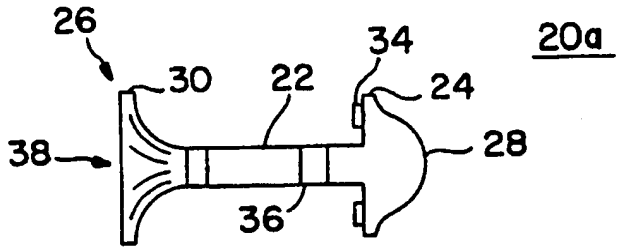

FIG. 1B

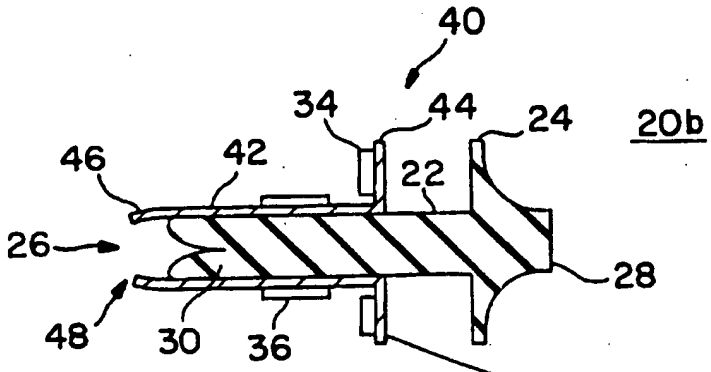

FIG. 2A

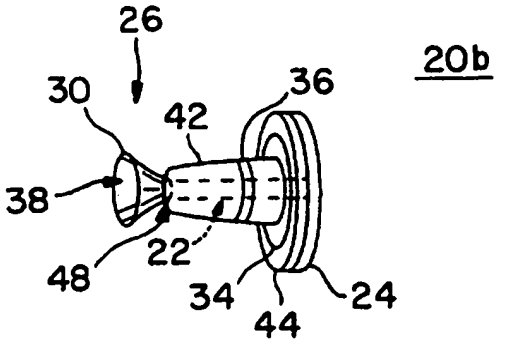

FIG. 2B

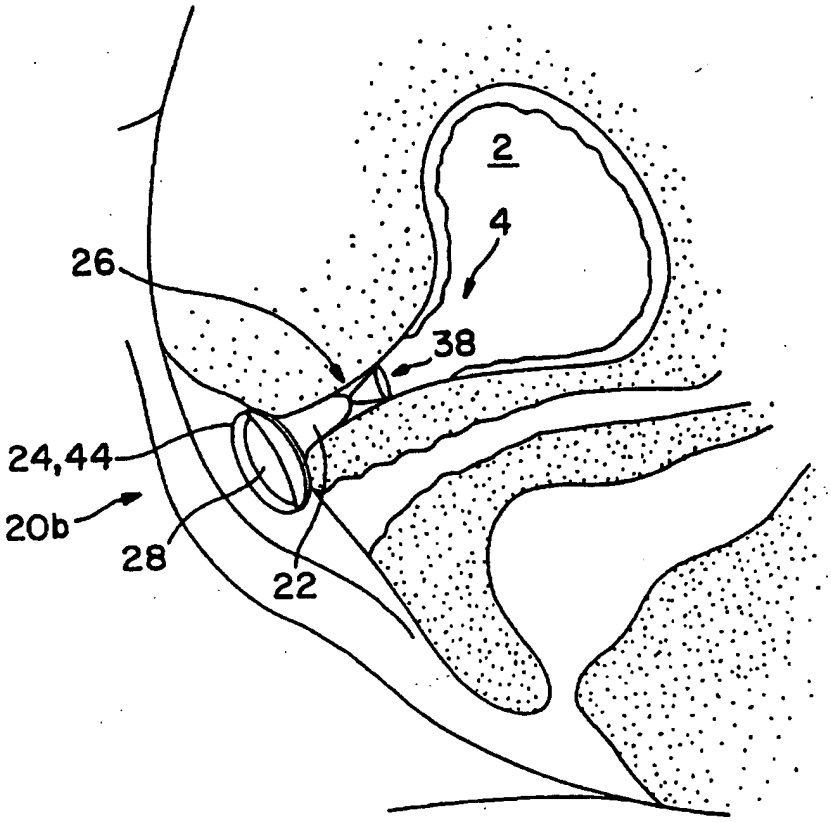

FIG. 2C

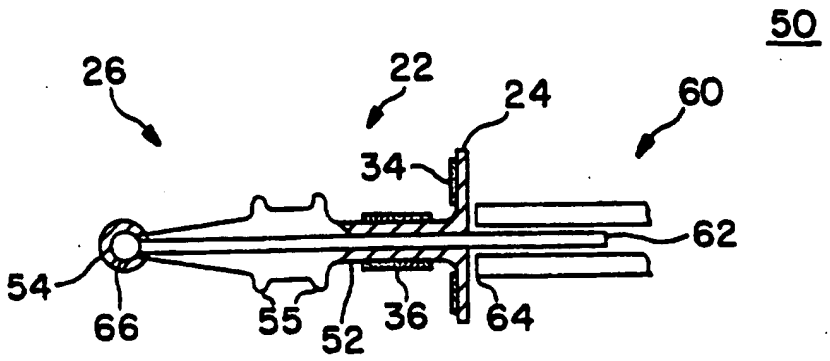

FIG. 3A

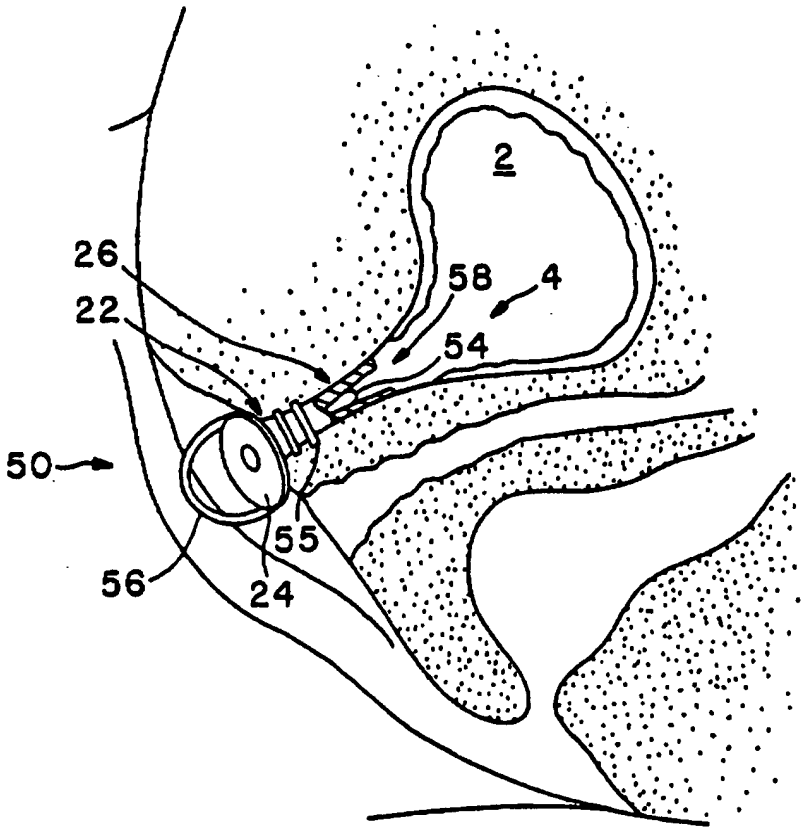

FIG. 3B

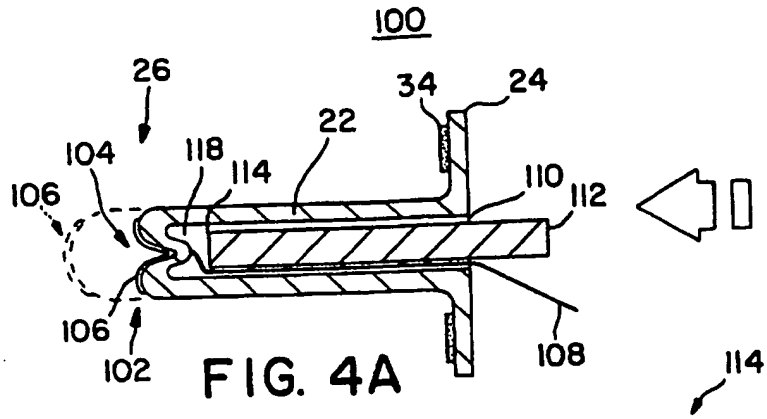

FIG. 4A

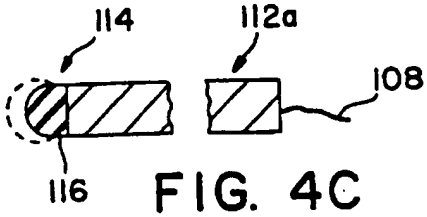

FIG. 4C

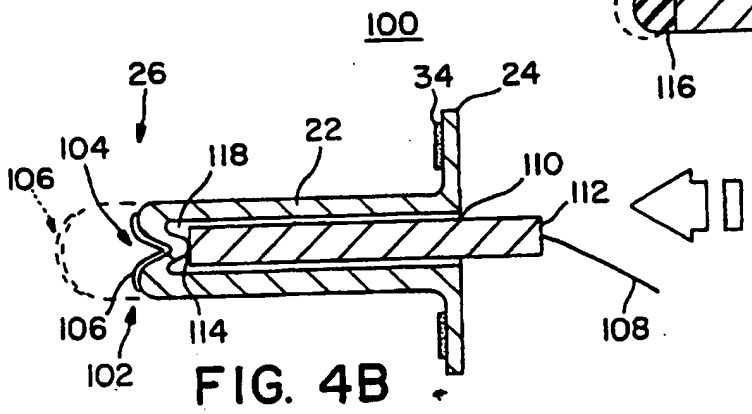

FIG. 4B

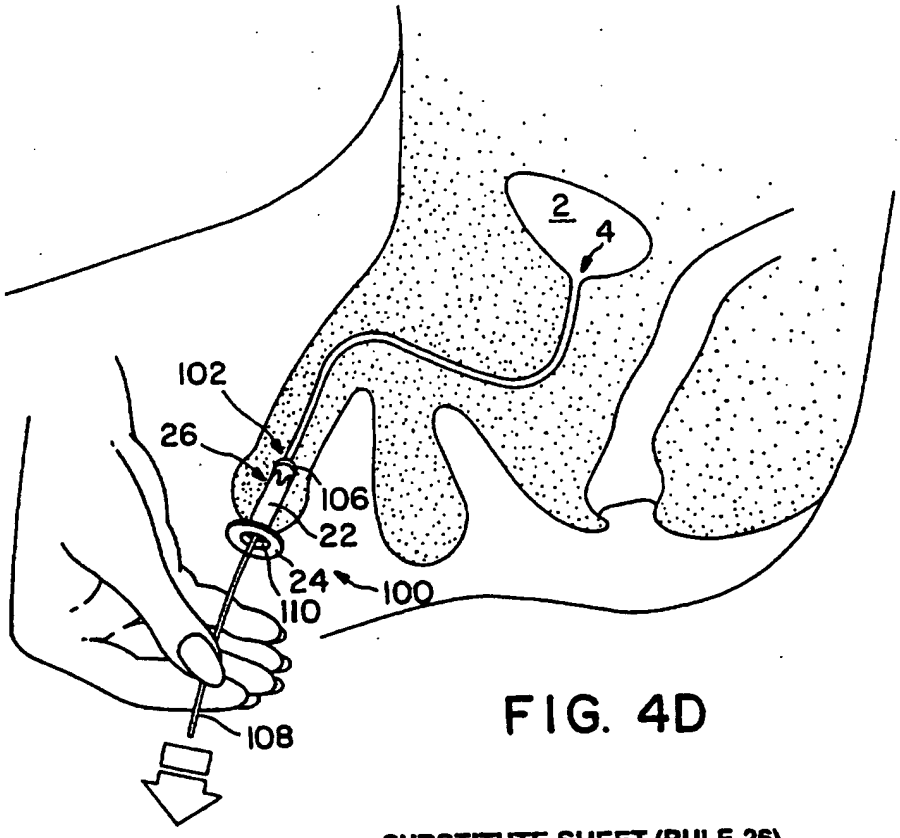

FIG. 4D

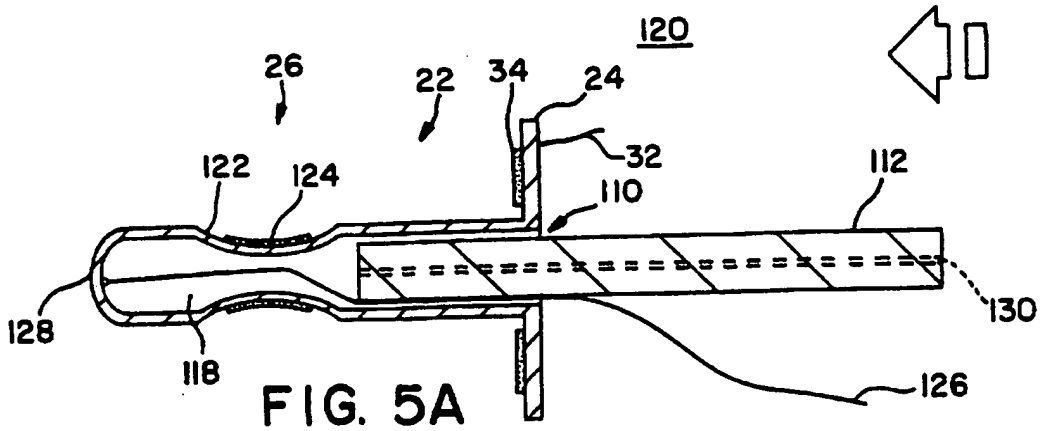

FIG. 5A

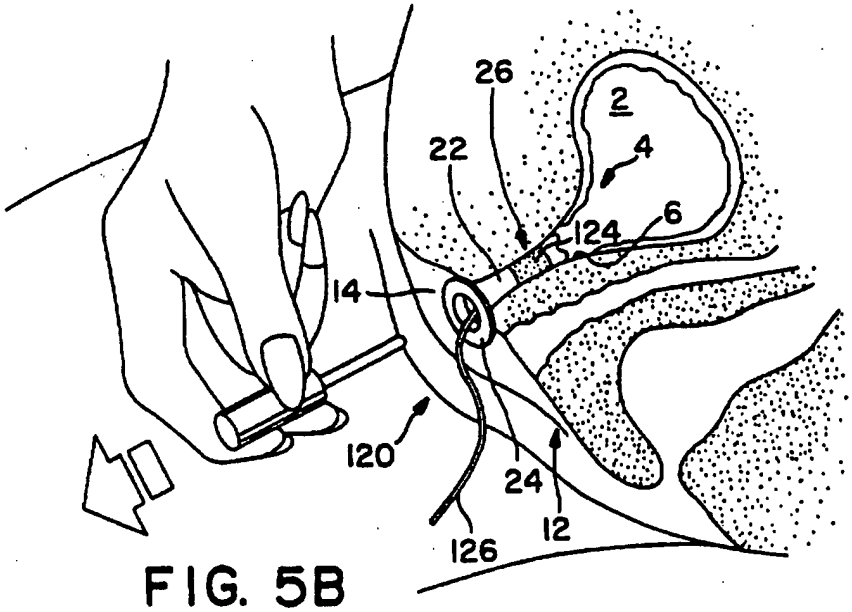

FIG. 5B

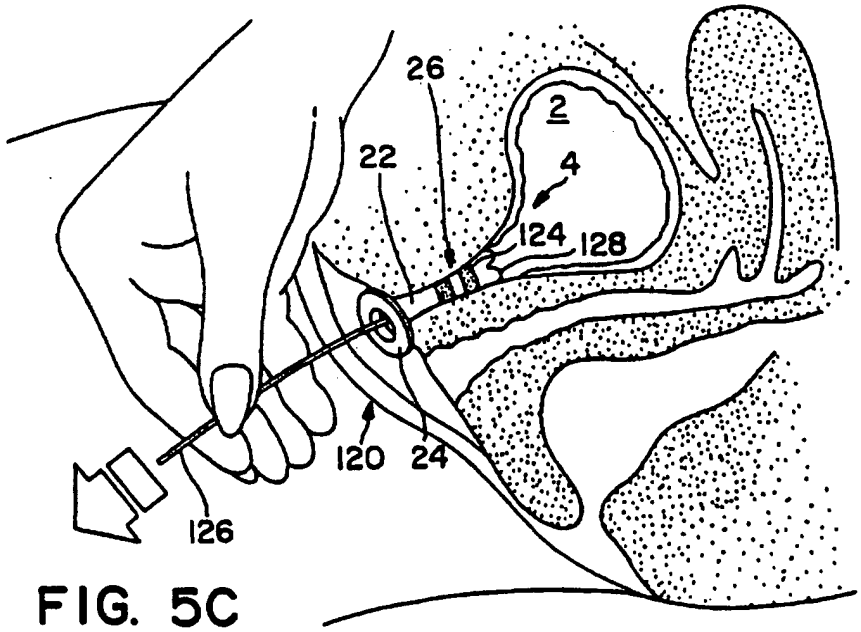

FIG. 5C

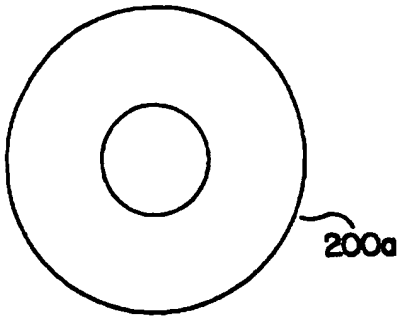

FIG. 6A

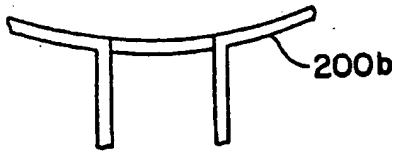

FIG. 6B

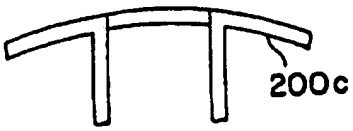

FIG. 6C

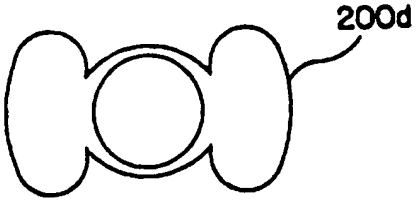

FIG. 6D

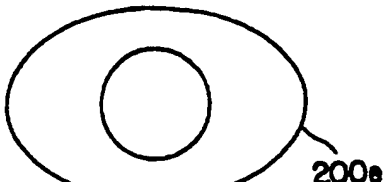

FIG. 6E

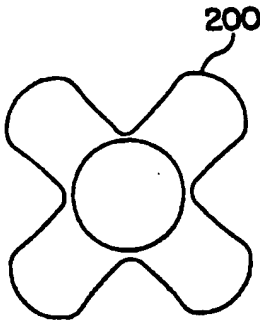

FIG. 6F

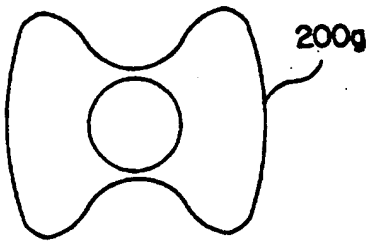

FIG. 6G

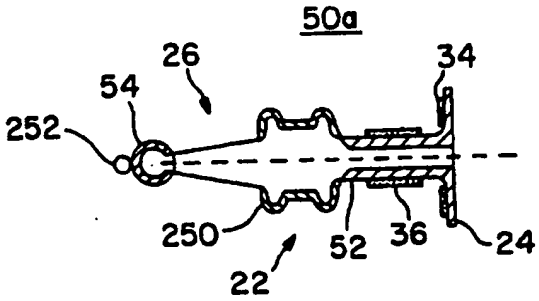

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB97/00141

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 5/48
US CL :128/885, DIG. 25
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/885, DIG. 25; 600/29-31; 604/329, 330, 346-353

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	NIELSEN, DURT K. The Urethral Plug: A New Treatment Modality For Genuine Urinary Stress Incontinence In Women, The Journal of Urology, Vol. 144, November 1990, pages 1199-1202.	1, 2, 4, 8, 51 ---------- 3, 5-7, 9-15, 19-50, 52-59, 68-80
Y	US 4,261,340 A (BAUMEL) 14 April 1981, entire document.	3, 5-7, 9-11
Y	US 5,336,208 A (ROSENBLUTH) 09 August 1994, entire document.	3, 5-7, 9-11, 23-50, 52-59, 68-80
Y	US 5,131,906 A (CHEN) 21 July 1992, entire document.	14, 15, 19-22

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 MAY 1997	05 JUN 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL A. BROWN Telephone No. (703) 308-2682

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB97/00141

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3,404,682 A (WALDRON) 08 October 1968, entire document.	35-50
Y	US 3,762,277 A (HIRACHMAN) 10 April 1973, entire document.	40
Y	WO 92/19192 A (DEBESS) 12 November 1992, entire document.	45, 49